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09/442,284	11/19/1999	RAPHAEL F. MELOUL	MENLO-103-DI	5637

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GARY W MCFARRON  
STEPHEN B HELLER  
COOK MCFARRON & MANZO LTD  
Ste 2850 200 West Adams  
CHICAGO, IL 60606

EXAMINER

GHAFOORIAN, ROZ

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 01/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/442,284

Applicant(s)

MELOUL ET AL.

Examiner

Roz Ghafoorian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 September 1996.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 19-22 and 38-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 19-22 and 38-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 is dependent on claim 18, which has been eliminated in the amendment filed on the September 23, 1997, thereby rendering the scope of the claim unascertainable.

***Claim Rejections - 35 USC § 102***

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

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published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claim 19, 38 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by U.S Patent No. 5,899,882 to Waksman et al. Waksman discloses an apparatus and method for delivery of a treating element, such as a radiation source, through a catheter to a desired site in the intraluminal passageways of a patient. The catheter is sized for insertion of the distal end portion through the vascular system of a patient to a selected area to be treated. After the treating element is loaded into the lumen pressurized blood-compatible liquid, such as sterile saline solution or sterile water, is introduced via liquid source through a port in the proximal end of the lumen behind the treating element. The liquid which provides the motive force for moving the treating element may be allowed to exit from the distal end of the catheter. (Col. 6, lines 60-65) Waksman also discloses a three-lumen catheter system with a transfer device containing treating elements and connected to the proximal end of a three lumen catheter tube. (Col. 8, lines 6-10) The third port opens into the third bore of the body and is adapted to receive a guide wire to aid in positioning the distal end of the catheter tube within a patient (col. 8, lines 25-30).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bagaoisan et al U.S Patent No. 5498240, and further in view of Bennett et al U.S Patent No. 4838881. Bagaoisan discloses an invention which relates to the field of intravascular catheters, which are advanceable over a guide wire into a desired region of a patient's Vasculatur, for therapeutic or diagnostic procedures therein. The intraluminal catheter of the invention has an elongated shaft having a proximal shaft section with at least one inner lumen extending therein and a distal shaft section with an inner lumen extending therein which is in communication with the inner lumen of the proximal shaft section. (Col.2 lines 30-45) Bagaosian, however, does not teach the lumens of the cathere having an ellepitac cross section. Bennett disclose a multilumen catheter comprises separate proximal IV tubes of substantially circular cross-section welded in fluid communication with each of the substantially elliptical-shaped lumens of the catheter. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to have combined the two studies. Because as states by Bennett, elliptically shaped lumens essentially eliminate flow problems caused by lumen wall junctures while at the same time using available catheter cross-section area more efficiently than circular-shaped lumens. Whereas a case can be made that eliptically shaped lumens are optimal for the design of a multilumen catheter. ( Col.2, lines 26-30)

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4. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bagaosian as applied to claim 21 above, and further in view of Bennett and Waksman. As described above Bagaosian discloses an invention, which relates to the field of intravascular catheters. Bennett discloses a multilumen catheter comprises an elliptical-shaped lumens. Bennett nor Bagaosian, however, do not teach radiopaque material at the distal end of the lumen. Waksman discloses a catheter which is closed by a molded tip plug, preferably of radiopaque material, bonded to the ends of the inner and outer tubes. Radiopaque marker bands may also be incorporated on the distal end portion of the elongated catheter tube to aid in placing the elongated tube within the body at the selected site. (Col. 17, lines 47-50).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to have combined the studies, because according to Waksman radiopaque markers aid in placing the elongated tube within the body at the selected site. (Col 19, lines 5-10)

5. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waksman as applied to claim 19 above, and further in view of Bressler et al U.S Patent No. 5466223. Assuming claim 20 is an independent claim and is not limited by claim 18. Waksman discloses an apparatus and method for delivery of a treating element, such as a radiation source, through a catheter to a desired site in the intraluminal passageways of a patient, with a detent in the center of the transfer device. Waksman, however does not contain a cantilever arm axially. Bressler discloses a needle

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assembly which includes both a detent and a cantilever arm .Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to have combined the studies, because according to Bressler cantilever allows for a snapping motion which provides an audible indication to the user that the locking had taken place. (Col.9, lines 45-50)

6. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waksman as applied to claim19 above, and further in view of Rosseman et al U.S Patent No. 5395332. . As discussed above Waksman disclose an apparatus and method for delivery of a treating element, such as a radiation source, with multiluminal catheter. Waksman, however, does not teach the use of high density/low density polyethylene on the lining of the lumen. Rosseman discloses a catheter for use in angioplasty which does utilize density polyethylene. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to have combined the studies, because according to Rosseman Polyethylene is a relatively lubricous, flexible and high strength material. (Col.8, line 8-11)

7. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waksman as applied to claim19 above, and further in view of Mawad et al U.S Patent No. 5498227. As discussed above Waksman disclose an apparatus and method for delivery of a treating element, such as a radiation source. Waksman protects its user against radiation by utilizing a carriage which the radiation source is loaded in to. The

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carriage is preferably made of a material and has sufficient thickness to protect the user against unnecessary exposure to radiation when the treating elements are radioactive.

(Col.8, lines 46-50) Wakman, however does not disclose a shield on the tube. Mawad discloses a radiotherapy device comprising a radioactive wire adapted to deliver an intended dosage of radiation to a lesion or other selected body tissues. The wire of radioactive material preferably comprises an inner core about which is disposed an outer buffer layer of platinum or other suitable metal of high atomic number. The outer buffer layer may comprise a relatively thin, continuous wire of round, flat, or other suitable cross-section, wrapped in spiral or helical fashion about the inner core, and is adapted to attenuate the radiation. (Col.2, lines 11-15)

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to have combined the studies, because it would be obvious to a method of protection against the potential exposure of radiation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Ghafoorian whose telephone number is 703-305-2336. The examiner can normally be reached on 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552.

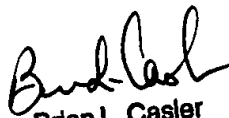
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



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RG  
December 28, 2001

  
Brian L. Casler  
Primary Examiner